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8 UNITED STATES DISTRICT COURT
9 CENTRAL DISTRICT OF CALIFORNIA
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11 Biomedical Device Consultants &
12 Laboratories of Colorado, LLC,

13 Plaintiff,

14 v.

15 ViVitro Labs, Inc.

16 Defendant.

Case No. 2:23-cv-04291-RGK-E

**DECLARATION OF CRAIG
WEINBERG, PH.D.**

17 I, Craig Weinberg, hereby declare and state as follows:

18 1. I am the former CEO and currently the Chief Technical Officer of
19 Biomedical Device Consultants & Laboratories of Colorado, LLC (“BDC”). I
20 make this Declaration in connection with BDC’s motion for a preliminary
21 injunction. I have personal knowledge of the facts herein, and if called as a
22 witness, I could and would testify competently thereto.

23 2. I received my Ph.D. in the area of Mechanical Engineering with a
24 focus in cardiovascular fluid dynamics from the University of Colorado in 2003. In
25 early 2011, I began to serve on the US sub-committee and then, as of January of
26 2015, began serving on the parent international committee ISO/TC 150/SC 2/WG
27 1, which is the group that creates the international guidance documents for design
28 verification/validation evaluation of heart valves and heart valve repair devices.

1 As a result, I am very familiar with all the commercially available products that are
2 part of the functional performance evaluation of prosthetic heart valves, both real-
3 time and accelerated, utilized during the verification/validation testing of the
4 associated devices.

5 3. In 2006, I joined BDC as its president. In about February 2008, a
6 team of three people—me, Benjamin McCloskey, and Dr. Steven Weinberg—
7 began researching and designing a new prosthetic heart valve and venous valve
8 durability testing system. The dedication of a three-person research team to this
9 project was a significant investment for BDC. Though BDC currently has five or
10 six employees devoted to working on its testing equipment development and eight
11 or nine employees working on its test equipment assembly, back at the time of the
12 invention in 2008, the entire company was only on the order of six full-time
13 employees.

14 4. The nature of BDC's business requires that it make these types of
15 significant investments in research and development. BDC's customers are those
16 that wish to test medical devices, often the medical device manufacturers
17 themselves testing the device to obtain regulatory approval. The medical device
18 industry is an innovative industry—new and improved medical devices enter the
19 market all the time. These newer devices often require state of the art testing
20 systems for their evaluation. Prosthetic heart valves have seen significant
21 improvements in the past decades, resulting in larger sizes and different methods
22 for securing devices in place within the human body (*e.g.*, transcatheter heart
23 valves). This has required similar innovations in the equipment available to test
24 the valves. Therefore, to stay competitive, BDC must keep pace with the
25 innovation of both its customers and its competitors.

26 5. Our research, with respect to heart valve durability test equipment,
27 eventually led to the issuance of several patents, including U.S. Patent No.
28

1 9,237,935 (“the ’935 Patent” or “the Patent-in-Suit”). I am a named inventor on
2 the ’935 Patent, among other patents.

3 **A. BDC’s Innovative VDT-3600i System Was Designed to**
4 **Accommodate Cutting-Edge Devices Using Superior Technology**

5 6. Before the Patent-in-Suit, heart valve durability testing systems on the
6 commercial market used designs that resulted in minimal control of the differential
7 pressure rate and spikes associated with valve closure that could result in
8 unnecessary early deterioration of the test valves and potential false test failures.
9 To better manage valve closing dynamics and differential pressure spikes, and thus
10 better comply with the durability testing standards, my co-inventors and I
11 developed a novel test system that placed an excess volume area on the outflow
12 side of a test sample valve. In one implementation, a volume of test system fluid
13 was “stored in an excess volume area during a system driving stroke that opens the
14 valved prosthetic device,” and “released during a return stroke that closes the
15 valved prosthetic device.” ’935 Patent at 3:14-18. In this way, the excess volume
16 area aids in controlling differential pressure spikes.

17 7. One type of “excess volume area” is a “compliance chamber.” A
18 compliance chamber is an area usually filled with air or gas within a test system
19 that permits a change in its volume with an associated change in system pressure.
20 In our design, we positioned a compliance chamber downstream of the test sample.
21 It acts similar to a spring and stores pressure in the system during the “drive” phase
22 (the phase the opens the test valve) and then releases it during the “return” phase
23 (the phase that closes the valve). Additionally, our patents describe a variety of
24 types of excess volume areas and compliance chambers.

25 8. The Patent-in-Suit and the products incorporating its invention
26 revolutionized the market for heart valve durability testing systems by providing an
27 accelerated testing device with an excess volume area on the outflow side of the
28

1 valve. BDC has commercialized the Patent-in-Suit through a product known as the
2 VDT-3600i heart valve durability tester.

3 **B. The VDT-3600i System Quickly Rendered Obsolete Competitors’**
4 **Test Systems to Become the Market Leading Test System**

5 9. The VDT-3600i has been a tremendous success. When it was
6 launched around 2010, it was a unique and differentiated product. It was the only
7 testing system on the market that provided an excess volume area in a return
8 chamber, downstream of the valve to store fluid during the driving phase of the
9 system, *i.e.*, when under compression. This excess volume area and use of a non-
10 regular driving waveform are significant improvements in accelerated test system
11 design. The excess volume area further provided for management of the rate of
12 pressure which improved our system’s ability to test heart valves at an accelerated
13 rate in an efficient and controlled manner, helping to avoid and control undesirable
14 pressure spikes.

15 10. The market for heart valve durability testing systems is highly
16 specialized and therefore is also very small.

17 11. When the VDT-3600i was released around 2010, the only competitors
18 were Defendant ViVitro Labs and Dynatek Labs. Dynatek’s system, however,
19 used old, outdated technology. As a result, it was, and is, not considered a viable
20 alternative in the marketplace for the latest valve technology and currently has few
21 sales, if any.

22 12. ViVitro’s then-current testing system—the HiCycle Durability
23 Tester—had a number of issues that made it unattractive to consumers in
24 comparison to the VDT-3600i.

- 25 a. ViVitro’s system relied on movement of an artificial heart valve
26 through fluid to create the valve opening and closing, not
27 movement of fluid through a valve, which is thus not testing the
28 valve in clinically representative manner.

1 b. ViVitro's system was too small to accommodate the larger heart
2 valve products of today.

3 c. ViVitro's system possessed multiple test stations that were driven
4 by a single motor.

5 d. ViVitro's system required balanced valves for testing.

6 Specifically, testing could only be performed with a balanced
7 number of valves in the system, and with valves of the same size
8 paired with each other on the system to be on balance.

9 e. ViVitro's system had only one pressure sensor for all six valves.

10 13. Once the VDT-3600i entered the market, ViVitro's technology was
11 deemed not as commercially relevant to, or an equivalent of the VDT-3600i.

12 14. Therefore, as a superior and unique product, the VDT-3600i rapidly
13 (within five years) became the industry standard for heart valve durability testing
14 systems.

15 15. To the best of my knowledge, there are currently only four
16 competitors in the market: my company BDC, Defendant ViVitro (which until
17 recently was promoting its obsolete technology), TA Instruments-Waters LLC, and
18 Dynatek Labs. To my knowledge, BDC's competitors have a minimal amount of
19 market share.

20 16. BDC's VDT-3600i currently has about a 70-75% share of the
21 worldwide market for heart valve durability testing systems, and an 80-85% share
22 of the U.S. market.

23 **C. The VDT-3600i System Is Vital to BDC's Business Success**

24 17. Market share in the heart valve durability testing equipment market is
25 extremely important due to the incumbency effects. A single testing system can
26 only test a few devices at a time. For example, both BDC and ViVitro sell systems
27 that test a maximum of six prosthetic heart valves at a time. To bring a new
28 prosthetic valve device to market, however, medical device manufacturers need

1 testing data from many, often dozens, of sample devices. Therefore, testing system
2 customers need multiple systems. Customers will generally purchase a single
3 testing system and run a short pilot program. If the pilot test is successful, the
4 customer will then purchase more of the same test systems from the same
5 manufacturer as part of a larger testing program for commercial use.

6 18. Customers generally do not buy testing equipment for a single device
7 from multiple sources in order to avoid introducing additional testing variables
8 (*i.e.*, differences between testing machines from different suppliers) into the test
9 data that would be submitted to the FDA, or international regulatory agencies. The
10 lifespan of valve durability testing equipment is often ten to fifteen years, meaning
11 that once a customer has decided which testing equipment to use, it will likely be a
12 long time before a competitor has the opportunity to usurp the place of an
13 incumbent. Moreover, if the customer buys additional equipment, it is most
14 common for customers to purchase the same type previously purchased, as
15 opposed to creating the variability discussed above with two systems.

16 19. A company's ability to maintain market share is crucial to its long-
17 term success. As I previously mentioned, research and development is vital to a
18 company in this industry so that it can keep pace with its customers and
19 competitors. In order to fund this research and development, BDC uses part of its
20 revenue from its sales to fund its research and development for new devices.

21 20. The VDT-3600i is of particular significance to BDC because it is
22 BDC's best-selling test system and is its highest-revenue generating product.
23 Therefore, lost sales of the VDT-3600i will negatively impact all of BDC's
24 business because it will have less revenue to fund its research and development
25 across its platform.

26 21. In this industry, market share is also often linked to reputation for
27 innovation. As I mentioned before, innovation is extremely important.
28 Accordingly, customers often make decisions based on reputation for innovation,

1 and a testing system supplier's long-term success is dependent on that reputation.
2 BDC has a reputation for innovation and associated customer goodwill. For
3 example, the BDC website has numerous customer testimonials discussing BDC's
4 work to innovatively solve problems posed by customers.
5 <http://www.bdclabs.com/about-us/client-testimonials/>. Contributing to BDC's
6 reputation for innovation is the fact that the VDT-3600i is a differentiated, patented
7 product for heart valve durability testing.

8 22. In addition to revenues deriving directly from the sale of VDT-3600i
9 Systems, BDC receives revenues for testing services performed under contract
10 with customers where BDC conducts tests using the VDT-3600i.

11 **D. ViVitro Begins Marketing a Copycat Tester that Infringes the**
12 **Patent-in-Suit and Presents a Substantial and Unique Risk to BDC**

13 23. However, ViVitro has threatened to change the status of VDT-3600i
14 as a unique product, when it started advertising and marketing at trade shows its
15 copycat tester that it claims will soon be available, the ViVitro ADC Heart Valve
16 Durability Tester.

17 24. The ADC Heart Valve Durability Tester mimics the VDT-3600i, and
18 moves away from the prior art in the following ways:

- 19 a. ViVitro's prior system moved the heart valve through the fluid, but
20 the new ADC Heart Valve Durability Tester moves the fluid
21 through the heart valve (like the VDT-3600i).
- 22 b. ViVitro's prior system was too small to accommodate the larger
23 heart valve products of today, but the new ADC Heart Valve
24 Durability Tester has chambers designed to "fit any valve size and
25 geometry" (like the VDT-3600i).
- 26 c. ViVitro's prior system was driven by a single motor, but the new
27 ADC Heart Valve Durability Tester has multiple linear
28 electromagnetic motors (like the VDT-3600i).

1 d. ViVitro's prior system required balanced valves for testing, but the
2 new ADC Heart Valve Durability Tester has independent test
3 modules that can test any number of valves of different sizes (like
4 the VDT-3600i).

5 e. ViVitro's prior system had only one pressure sensor for all six
6 valves, but the new ADC Heart Valve Durability Tester has
7 independent sensors for each valve (like the VDT-3600i).

8 f. As described in U.S. Patent No. 9,237,935 and as used in the VDT-
9 3600i, the new ADC Heart Valve Durability Tester uses an excess
10 volume area that can function to counteract pressure spikes.

11 25. ViVitro's ADC Heart Valve Durability Tester is harmful to BDC in a
12 way that the other competing products are not. As described above, Dynatek's
13 system is obsolete and predates the Patent-in-Suit.

14 26. TA Instruments' product does not present the same competitive risk as
15 ViVitro's product. TA Instruments is a large company with many types of
16 equipment for testing products not exclusive to the medical device industry (i.e.,
17 batteries, biopharma, electrodes, pharmaceuticals and medical devices). To my
18 knowledge, TA Instruments offers only one product related to testing of heart
19 valves, and does not offer testing services of the type offered by BDC and ViVitro.
20 TA Instruments does not have the reputation and credibility in the heart valve
21 testing industry enjoyed by BDC and ViVitro. For these reasons, although TA
22 Instruments has been on the market for nearly a decade, it has not achieved
23 substantial market share in a way that threatens BDC. Further, ViVitro has a
24 greater reputation for innovation than either of those two competitors. As I stated
25 above, innovation is key to attracting and retaining customers.

26 27. By contrast, ViVitro is a greater competitive threat because it is well-
27 known in the market for heart valve testing. According to the ViVitro website, it
28 was founded in the mid-1970s and its first development project was to build a heart

valve tester. <https://vivitrolabs.com/company/>. ViVitro has been well-known in the industry since at least the mid-1990s. I am aware of only six pieces of equipment offered by ViVitro, and four of those pieces relate to heart valve testing.

28. Prior to BDC's ground-breaking invention, embodied in the VDT-3600i, ViVitro was a leading provider of heart valve testing equipment, through its HiCycle accelerated durability tester. With BDC's introduction of the innovative VDT-3600i product, it disrupted the industry and captured the vast majority of market share for accelerated durability testers of heart valves, including most of ViVitro's market share. Now, a dozen years later, ViVitro is seeking to recapture this market share by introducing an infringing system.

29. BDC faces a far, far greater risk from ViVitro—a company with a reputation for innovation, and which offers the same testing services as BDC—than it ever has from either Dynatek or TA Instruments. ViVitro's coming out with a truly competitive product will dramatically impact BDC's reputation as the leading innovator in heart valve durability testing equipment and damage the good will BDC has spent years building based on its patented, innovate product.

30. Even before ViVitro introduced its copy of the innovative VDT-3600i tester, it has sought to replicate the testing services offered by BDC. For years, BDC has offered an expanded array of testing services. In or around May of 2021, ViVitro changed its website to provide service offerings that closely mimic the offerings of BDC. The chart below summarizes this shift:

ViVitro Testing (4/18/2021) - Old	ViVitro Testing (6/20/2021) New (to match BDC)	BDC Testing
<ul style="list-style-type: none"> • Durability Testing • Pulsatile-Flow Testing 	<ul style="list-style-type: none"> • Stents and Equivalent • Stent Graft and Vascular Prosthesis • Catheters 	<ul style="list-style-type: none"> • Stent & Stent Graft Testing • Vascular Graft Testing • Catheter Testing

<ul style="list-style-type: none"> • Steady Flow Testing 	<ul style="list-style-type: none"> • Heart Valve Replacement and Repair • Metallic Frame Based Systems • Circulatory Support Devices • Guidewires • Other Cardiovascular Devices 	<ul style="list-style-type: none"> • Heart Valve Testing • Coating & Particulate Testing • MRI Compatibility Testing • General Testing
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31. ViVistro's introduction of the VDT-3600i uniquely threaten BDC's market share and viability, because ViVistro is a recognized player in the heart valve testing market, and is seeking to offer the same services and same products to usurp BDC's customers. By offering a copy of BDC's flagship product that utilizes its patented innovation, especially in addition to the copycat nature of its new offerings, ViVistro will cause BDC to lose its reputation as an innovator and will take away BDC's market differentiator.

32. ViVistro's sales will not only adversely affect sales of BDC's system, but also BDC's related products and services.

33. Even one lost sale to ViVistro is a significant threat to BDC because the market is very small. Systems are expensive, and BDC only sells between twenty-five and thirty-five systems a year. The market is therefore sensitive to change. With ViVistro on the verge of launching a copycat product, BDC is in immediate threat of losing its market lure as a unique, patented product. This will lead to BDC losing more market share and losing its reputation for innovation.

E. ViVitro Markets Its Infringing Product, BDC Alerts ViVitro to Its Infringement, and ViVitro Disregards the Notice and Continues to Market Its Product

34. I first became aware of the ADC Heart Valve Durability Tester last summer, when I became aware of literature disseminated by ViVitro. I reached out to ViVitro by email, to politely express my concern. ViVitro responded, but did not allay my concerns or provide additional information on the functioning of the product.

35. On August 22, 2022, counsel for BDC sent a letter to ViVitro notifying it that the ADC Heart Valve Durability Tester infringes at least claim 1 of the Patent-in-Suit and claim 25 of U.S. Patent No. 8,627,708. With this letter, BDC provided a claim chart and a copy of ViVitro's sales brochure with annotations to map it to the patent claim. As of that time, I had not actually seen a product, but understood one would be on display at an upcoming trade show.

36. ViVitro responded, through Canadian counsel. Rather than outright deny infringement, ViVitro noted that "the elevated chamber you identified as 'Feature F'" does not meet the limitations of claim 1 of the Patent-in-Suit.

37. Despite these cautions, ViVitro advertised the ADC Heart Valve Durability Tester on its website, and permitted users to download a brochure. Attached as **Exhibit 1** is a true and correct copy of an archived version of ViVitro's website from last fall, which includes a link to download the brochure. Attached as **Exhibit 2** is a true and correct copy of the ADC Heart Valve Durability Tester sales brochure that I obtained last summer.

38. In mid-September 2022, both BDC and ViVitro attended the Transcatheter Cardiovascular Therapeutics Conference (the "TCT Conference") in Boston, Massachusetts. This conference, which was held September 16-19, 2022, is described as "the world's premier educational meeting specializing in interventional cardiovascular medicine." At the TCT Conference, ViVitro

1 displayed the ADC Heart Valve Durability Tester in its booth. I observed the
2 tester, and generally saw it in operation.

3 39. At the TCT conference, I spoke with ViVistro's President Karim
4 Mouneimne about the ADC Heart Valve Durability Tester. I explained to Mr.
5 Mouneimmne that BDC developed its products and patent portfolio at considerable
6 expense, and that BDC is committed to protecting its investment and the rights that
7 its patent provides. I asked Mr. Mouneimmne to provide me with further
8 information about the operation of the ADC Heart Valve Durability Tester. He
9 declined, but suggested that a publication would issue in approximately six weeks
10 that would provide additional information about its operation. I have looked for,
11 but been unable to find, any such publication.

12 40. In early November 2022—*i.e.*, six weeks after my conversation with
13 Mr. Mouneimmne—BDC wrote to ViVistro again, to follow up on ViVistro's letter
14 claiming that BDC had misidentified a feature, in light of "what BDC ha[d] been
15 able to learn about the Vivitro ADC Heart Valve Durability Tester" and the
16 conversation I had with Mr. Mouneimne. BDC provided a revised annotated sales
17 brochure, identifying all of the limitations of claim 1 of the Patent-in-Suit (the '935
18 Patent).

19 41. ViVistro then advised it would need to retain a U.S. lawyer to respond.
20 After prodding for a response, nearly three months later—on January 31, 2023—
21 ViVistro provided its substantive response through U.S. counsel. In its response,
22 ViVistro did not try to argue that the ADC Heart Valve Durability Tester does not
23 meet the limitations of claim 1 of the Patent-in-Suit. Instead, it simply argued that
24 the Patent-in-Suit is invalid, while offering clearly different and unrelated prior art.

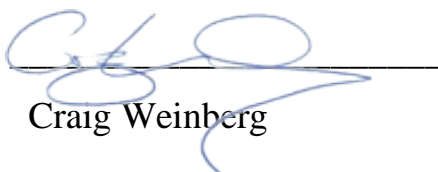
25 42. ViVistro continued to market its ADC Heart Valve Durability Tester at
26 the MD&M West conference in Anaheim, California, recently held February 7-9,
27 2023. I observed the ADC Heart Valve Durability Tester at ViVistro's booth.
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1 43. ViVistro has shown that it plans to continue marketing to U.S.
2 purchasers, both in the United States and abroad. There was recently a technical
3 conference (Heart Valve Society annual meeting) in Malaga, Spain from March 29
4 through April 1, 2023. ViVistro and many other U.S. companies and customers
5 attended this technical conference. ViVistro's website invited attendees to "Meet
6 with ViVistro Labs at HVS 2023," immediately followed by a product description
7 of the ADC Heart Valve Durability Tester, and a link to download the sales
8 brochure. A copy of this material, accessed on March 21, 2023, is attached as
9 **Exhibit 3.**

10 44. Based on my personal observation at trade shows, I have observed
11 ViVistro actively marketing and selling the ADC Heart Valve Durability Tester. I
12 have been informed by other market participants that ViVistro is currently unable to
13 ship functioning ADC Heart Valve Durability Testers to customers, but that it
14 expects to deliver ADC Heart Valve Durability Testers in the fall of 2023.

15 45. A preliminary injunction is necessary to prevent ViVistro from
16 importing and distributing the ADC Heart Valve Durability Tester to U.S.
17 customers. If an injunction is not granted, BDC will suffer long-term effects and
18 irreparable harm, due to the long-term use of these products, the effect on BDC's
19 reputation, the competitive harm to BDC in light of ViVistro's reputation in the
20 market, and the additional sales and non-monetary benefits enjoyed by BDC as an
21 innovator in this area.

1 I declare under the penalty of perjury under the laws of the United States of
2 America that the foregoing is true and correct. Executed on June 23, 2023 in
3 Wheat Ridge, Colorado.

4
5 By: 
6 Craig Weinberg
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